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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,165	11/09/2000	Robert Denham Pinnock	5771-01-EMA	2583

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EXAMINER

DELACROIX MUIRHE, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/700,165	Applicant(s) PINNOCK ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-26 and 28-42 is/are pending in the application.
 4a) Of the above claim(s) 31-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-9, 11, 16-19, 24, 26, 29 and 30 is/are rejected.
- 7) ☒ Claim(s) 3-6, 10, 14, 15, 20-23, 25 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is responsive to applicant's amendment received Nov. 15, 2004.

Claims 12, 13, 27 are cancelled. No claims are added. Claims 1-11, 14-26, 28-42 are currently pending.

Claims 31-42 are withdrawn from consideration. Please note: the previously non-elected claims were examined to their full scope, and the previous election requirement mailed April 9, 2003 is withdrawn.

The previous claim objection set forth in paragraph 1 of the office action mailed Aug. 12, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 103(a) set forth in paragraph 2 of the office action mailed Aug. 12, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous double patenting rejection set forth in paragraph 3 of the office action mailed Aug. 12, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, upon further reconsideration of the claims and the specification, the examiner respectfully submits the following new ground(s) of rejection.

Please note: the previously non-elected claims were examined to their full scope and the previous election requirement mailed Oct. 2, 2002 is withdrawn.

Finally, applicant's information disclosure statement received Nov. 28, 2004 has not been considered. An incomplete copy of the Blommaert et al. reference, i.e. only two pages, was submitted and therefore could not be considered.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to a method for preventing among other disorders, pancreatic and prostate cancer by administering to a subject in need thereof an effective amount of Formula (I).

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(2) The state of the prior art

As regards pancreatic cancer, the symptoms of pancreatic cancer occur late in the course of the disease. By diagnosis, 90% of patients have tumor that is locally advanced. Routine laboratory tests are often normal, and the most accurate and cost-effective method of diagnosing and staging pancreatic cancer is to perform CT as the first test. Other commonly performed tests are ultrasound and endoscopic retrograde pancreatography. Symptomatic treatment and treatment aimed at controlling the cancer are equally important. Treatment aimed at controlling cancer involves chemotherapy, radiotherapy, surgery or combinations thereof. There is no discussion or suggestion that pancreatic cancer can be *prevented* in patients. Please see the Merck Manual, pages 330-331.

Prostate cancer generally is slowly progressive and may cause no symptoms. Prostate cancer should be suspected on the basis of abnormal digital rectal findings, hypoechoic lesions on transrectal ultrasound (TRUS) or elevated serum levels of prostate specific antigen (PSA). However, diagnosis requires histologic confirmation. PSA is the most sensitive marker for monitoring cancer progression and response to therapy, yet its role in early detection and staging is still being evaluated. Treatment involves surgery, hormonal therapy, adjuvant therapy or combinations thereof. While a cure may be possible, the potential for a cure depends upon factors such as grade, stage and pretreatment PSA levels. Nowhere is there discussion or suggestion that prostate cancer can be *prevented* in patients. Please see the Merck Manual, pages 1918-1919.

(3) The relative skill of those in the art

The relative skill of those in the art is high. However, given the state of the art as set forth

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above, the artisan is currently unaware of any one particular agent that is effective in preventing prostate or pancreatic cancer. Furthermore, the burden of enabling the prevention or cure of these specific cancers would be much greater than that of enabling the treatment of these cancer for the purpose of alleviating, altering or ameliorating the cancer and its symptoms.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and cancer art is high. Additionally, the lack of significant guidance from the present specification or prior art with regard to the actual prevention of prostate or pancreatic cancer in a mammal, including a human, with the claimed compound as the active ingredient makes practicing the claimed method unpredictable.

(5) The breadth of the claims

The claims are specifically drawn to the prevention of prostate or pancreatic cancer as opposed to the prevention of “cancer” in general.

(6) The amount of direction or guidance presented

On pages 20-22 of the specification, applicant describes prophetic examples of “treating” prostate or pancreatic cancer “by means of standard pharmacological procedures.” However, the specification does not provide guidance as to how one of ordinary skill in the art would accomplish the objective of preventing pancreatic or prostate cancer in a patient or how a patient could be kept from even being susceptible to these forms of cancer. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active agents for preventing these types of cancer.

(7) The presence or absence of working examples

There are no working examples in the specification pertaining to the prevention of

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prostate or pancreatic cancer. As stated in paragraph (6), applicant describes prophetic examples of “treating” prostate or pancreatic cancer “by means of standard pharmacological procedures.”

(8) The quantity of experimentation necessary

In the absence of any sound evidence or scientific reasoning as to how the skilled artisan would extrapolate any results from the prophetic examples in the present disclosure directed solely to treating pancreatic or prostate cancer as being reasonably suggestive of preventing pancreatic or prostate cancer, the present disclosure is not determined to be enabling for the prevention of these specific cancers.

Additionally, in light of the state of the art, which conspicuously lacks recognition that pancreatic or prostate cancer can be prevented, and in view of the unpredictability of diagnosing these cancers for purpose of treatment only, it is highly unlikely, and the Office would require experimental evidence to support the contention, that the claimed compound(s) could actually prevent prostate or pancreatic cancer by simply administering, by any method, an amount of the claimed compounds.

Given what is presently claimed, what is presently disclosed, and given what is supported by adequate description in the specification, one of ordinary skill in the art would have no alternative recourse *but* undue experimentation in order to determine how the present invention could be used to prevent prostate or pancreatic cancer.

Finally, the term “preventing” circumscribes methods of absolute success. Since absolute success is not reasonably possible with most diseases/disorders, especially those having etiologies and pathophysiological manifestations as complex/poorly understood as cancer, the specification, which lacks an objective showing that pancreatic or prostate cancer can actually be

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prevented, is viewed as lacking an adequate written description of the same.

2. Claims 1-2, 7, 18, 19, 24, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “lung repair and lung development disorders” renders the claims vague and indefinite. This limitation is not defined by the claim, and the specification does not provide a description for the lung repair and development disorders that are within the scope of the invention. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

“The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all of the criteria for patentability and whether the specification meets the criteria of 35 USC 112, first paragraph with respect to the claimed invention.” Please see MPEP 2173.

Because the limitation “lung repair and lung development disorders” would invite subjective interpretations of whether or not a particular condition involving the lungs was included by or excluded from the present claims, the Examiner respectfully submits that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims do not meet the requirements of 35 USC 112, second paragraph.

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Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

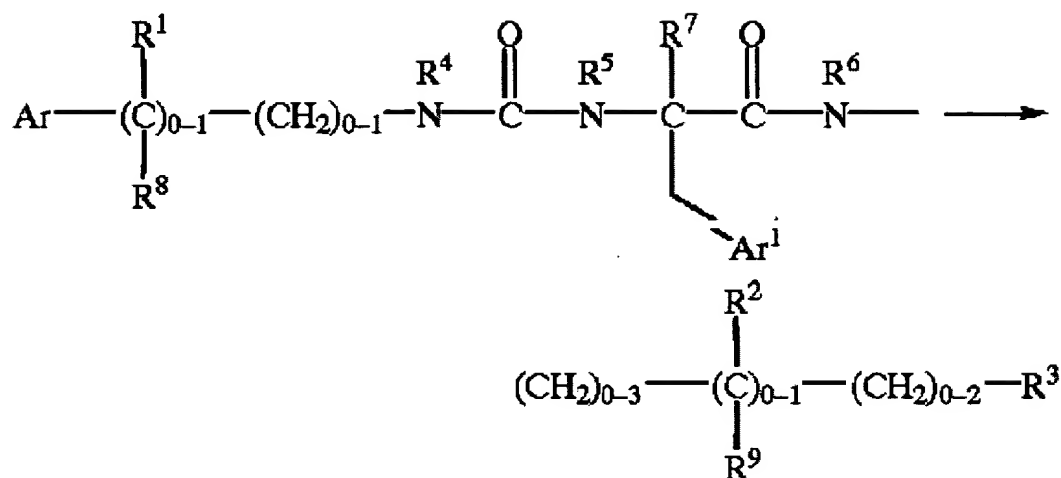
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 8, 9, 17, 18, 19 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horwell et al., 6,194,437 B1 (reference already of record).

Horwell et al. disclose methods for treating and/or preventing cancer by administering to a patient in need thereof an effective amount of the compound of Formula I

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I



or a pharmaceutically acceptable salt thereof wherein

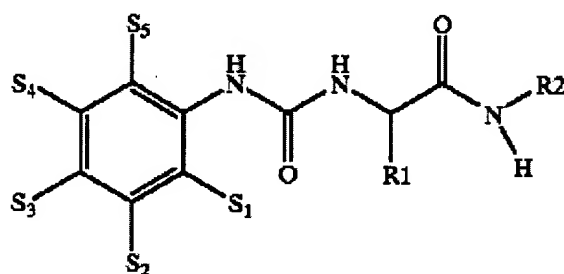
the substituents are defined at col. 2, lines 15-64. Please also see the abstract; col. 1, lines 55-63.

Horwell et al. do not specifically disclose treating or preventing prostate or pancreatic cancer. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat a specific form of cancer such as prostate or pancreatic cancer because one of ordinary skill in the art would reasonably expect the anti-cancer properties of a compound of Formula (I) to demonstrate activity against pancreatic or prostate cancer cells. Absent evidence to the contrary, it would have been obvious and reasonable to conclude from the disclosure of Horwell et al., that if the compounds of Formula (I) were administered to a patient suffering from prostate or pancreatic cancer, inhibition of these cancers would result thereby treating the patient.

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4. Claims 1, 2, 11, 16, 17, 18, 19, 26, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrie et al., 6,391,917.

Petrie et al. disclose a method of providing an analgesic effect in a subject in need thereof comprising administering to the subject an effective amount of a compound of the following formula



wherein the substituents are described in claim 4 as well as column 5-column 6. Please also see col. 4, lines 9-15; col. 8, lines 41-43; claims 1 and 4.

Petrie et al. do not specifically teach treating the specific painful conditions described in the claims, for example, neuropathic pain, cancer pain, postoperative pain, etc. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat the claimed painful conditions with the disclosed compounds because one of ordinary skill in the art would reasonably expect the analgesic inducing properties of the disclosed compounds to ameliorate pain associated with cancer, operations or neuralgia. Absent evidence to the contrary, it would have been obvious and reasonable to conclude from the disclosure of Petrie et al., that if these compounds were administered to a patient suffering from such painful conditions, analgesia would be induced and treatment of the pain would result.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 2, 8, 9, 17, 18, 19 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 6,194,437. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN ‘437 claim methods of treating cancer by administering to a patient in need thereof an effective amount of a compound represented by Formula (I).

The difference between the claims of the instant application and the claims of USPN ‘437 is the claims of USPN ‘437 recite a method of treating cancer in general, whereas the claims of the instant application claim specifically claim a method of treating or preventing pancreatic or prostate cancer.

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The scope of the claims of the instant application and the claims of USPN '437 overlap because the broader claims of USPN '437 encompass the more specific claims of the instant application. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat a specific form of cancer such as prostate or pancreatic cancer because one of ordinary skill in the art would reasonably expect the anti-cancer properties of the claimed compounds of Formula (I) to demonstrate activity against pancreatic or prostate cancer cells.

6. Claims 3-6, 10, 14-15, 20-23, 25, 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1,2,7-9,11,16-19,24,26,29 and 30 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

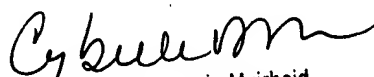
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

Feb. 21, 2006


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